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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/921,406	08/02/2001	Zohar Yakhini	10010313-1 (2003309-0012)	6019
22878	7590	06/29/2004	EXAMINER	
AGILENT TECHNOLOGIES, INC. INTELLECTUAL PROPERTY ADMINISTRATION, LEGAL DEPT. P.O. BOX 7599 M/S DL429 LOVELAND, CO 80537-0599			NICKOL, GARY B	
			ART UNIT	PAPER NUMBER
			1642	

DATE MAILED: 06/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/921,406

Applicant(s)

YAKHINI ET AL.

Examiner

Gary B. Nickol Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 21-25 is/are pending in the application.
- 4a) Of the above claim(s) 1-3 and 21-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4,25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Re: Yakhini *et al.*

Date of priority: 08/02/2001

***Response to Amendment***

The Amendment filed April 14, 2004 in response to the Office Action of December 12, 2003 is acknowledged and has been entered.

Claims 1-4, 21-25 are pending.

Claims 1-3, 21-24 have been withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to non-elected inventions.

Claims 4, 25 are currently under consideration.

**The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.**

***Election/Restrictions***

Claims 1-3 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The currently amended claims are now drawn to diagnosing an aggressive form of cancer comprising analyzing Wnt5a and at least one other gene- but not more than 19 independent genes from those listed in Claim 1---while the originally elected invention was examined to the extent that the claimed method only read on analyzing the expression of Wnt5A. Applicants reiterate previous arguments (Response, 04/14/04, page 15) that the invention is not just determining the expression of one gene out of twenty-one in order to

identify a tumor as aggressive or not-aggressive. Instead, the invention involves determining the expression of a combination of the listed genes to identify an aggressive or non-aggressive tumor. Applicants argue that "the breadth of protection necessary for adequate protection of the inventor's contribution to the art must include a claim listing all twenty genes". This argument has been considered but is not found persuasive for the reasons of record in the Action mailed 12-12-2003. Further, the restriction requirement was deemed to be proper and was made final in the previous action.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 1-3 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

#### ***Drawings***

The conditions for accepting color drawing do not appear to have been fully satisfied. While, Applicants have properly amended the specification and appear to have also paid the fee set forth in 37 CFR 1.17(h), there does not appear to be an actual petition filed under 37 CFR 1.84(a)(2). Clarification is requested. The Office will accept color drawings in utility or design patent applications and statutory invention registrations only after granting a petition filed under 37 CFR 1.84(a)(2) explaining why the color drawings are necessary.

#### **Rejections Maintained:**

Claim 4 remains rejected and new Claim 25 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject

Art Unit: 1642

matter which applicant regards as the invention for the reasons of record in the Action mailed 12/12/03, page 5. The claims recite “identifying the tumor as aggressive or non-aggressive based on the expression pattern of the genes”; however it remains unclear *how* the expression pattern provides a nexus for determining whether or not the tumor is aggressive or nonaggressive.

Applicants argue that the claims as written in light of the specification (Specification, page 51) are not indefinite to one of skill in the art reading the application. This argument has been considered but is not found persuasive as the specification has only illustrated one potential expression pattern. Applicant is reminded that the claims define the subject matter of the invention, and that the specification cannot be relied upon to read limitations into the claims. Thus, it is maintained that the claims lack an essential or critical step, and applicant’s arguments have not been found persuasive and the rejection is maintained.

#### **New Rejections:**

Claims 4, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iozzo *et al.* (Cancer Research, Vol. 55, pages 3495-3499, 1995) for the reasons of record in the Action mailed 12/12/03, pages 6-7. As set forth previously, Iozzo *et al.* teach a method of diagnosing a form of cancer comprising providing a genetic sample from a test sample of a tumor and analyzing expression of the Wnt5a gene wherein the cancer is a malignant melanoma. Specifically, Iozzo *et al.* identify (page 3498, 2<sup>nd</sup> column; page 3499, last paragraph) statistically high levels of Wnt5a expression in lung carcinomas, metastatic melanomas, and breast carcinomas. Hence, based on the high pattern of expression of Wnt5a in these tumors, the authors have identified tumors that possess the characteristics of aggressive versus non-

Art Unit: 1642

aggressive phenotypes. And, while Iozzo *et al.* do not specifically teach selecting a treatment regimen for an individual with the tumor based on whether the tumor is aggressive or non-aggressive; it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to include the step of selecting a treatment regimen (such as chemotherapy or surgical removal of the tumor) for an individual who has been diagnosed with any one of the aggressive or non-aggressive tumors diagnosed by Iozzo *et al.* One would have been motivated to do so because upon the diagnosis of an aggressive or non-aggressive form of cancer it is conventional in the field of oncology that clinicians present the patient with some type of treatment option to lower the risk of mortality.

Applicants agree (page 17) that while a clinician may be required to present a patient with a treatment option, the cited art does not teach that the treatment options for an aggressive tumor “may be different” than the treatment options for a non-aggressive tumor. Applicants further argue that Iozzo *et al.* do not teach or suggest that a different treatment be given for a tumor expressing Wnt5a versus a tumor found to not express Wnt5a. These arguments have been carefully considered but are not found persuasive because arguments that rely on particular distinguishing features are not persuasive when those features are not recited in the claims. In this particular case, the claims do not require that the treatment options be different for aggressive versus non-aggressive tumors nor do the claims recite treatment with an agent “known to inhibit Wnt5a activity”. Thus, applicant’s arguments have not been found persuasive and the rejection is maintained.

No claim is allowed.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 571-272-0835. The examiner can normally be reached on M-Th, 8:30-5:30; alternate Fri., 8:30-4:30.

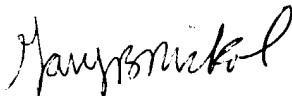
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1642

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gary B. Nickol Ph.D.  
Primary Examiner  
Art Unit 1642

June 28, 2004

  
**GARY NICKOL**  
**PRIMARY EXAMINER**